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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,616	12/01/2000	Arlindo L. Castelhana	1919/60390-G/JPW/GJG/CMR	5191

7590 02/11/2004

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New York, NY 10036

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,616

Applicant(s)

CASTELHANO ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-110, 114-124, 126-131 and 133-135 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76, 123, 124, 126-131 and 133-135 is/are rejected.
- 7) ☒ Claim(s) 77-110 and 114-122 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed November 14, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 76-99, 105, 110, 124, and 133 have been amended.

Claims 125 and 132 have been canceled.

Claims 134-135 have been added.

Remarks drawn to rejections of Office Action mailed August 11, 2003 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(a) rejection: which has been overcome by applicant's amendments and has been withdrawn.

An action on the merits of claims 16-110, 114-124, 126-131, and 133-135 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

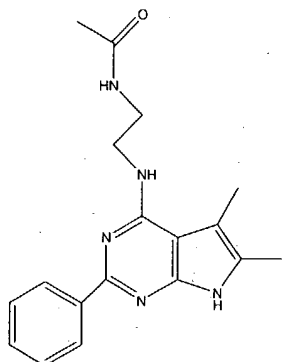
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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

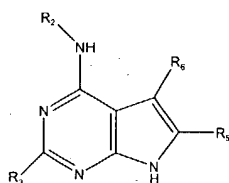
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 76 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 6,686,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Markush groups of both claim sets comprise a compound of the same structure. Claim 76 comprises a compound having the following structure:



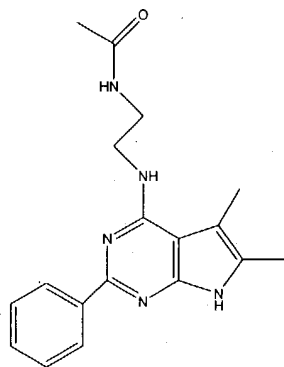
when R_6 and R_5 are methyl; and R_1 is acetamido ethyl.

Claim 1 of US 6,686,366 comprises a compound having the following structure:



and R_2 is optionally acetamido ethyl; R_5 and R_6 are optionally alkyl (methyl); and R_3 is optionally an aryl ring, thus providing a compound having the structure:

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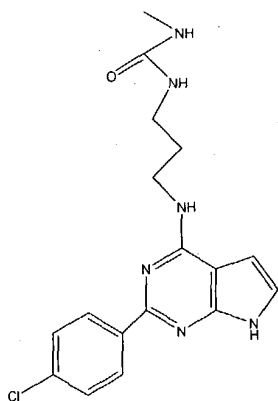


which is the same as in the instant application. Moreover, claims 2 and 3 of '366 limit R_3 to phenyl; claims 4, 5, and 10 limit R_5 and R_6 to methyl. Claim 6 and 7 of '366 also provide, when $m=0$, that the moiety in the R_2 position is acetamido ethyl (it is noted that the variable R_2 on the structure of claim 6 is believed to be a typographical error and the examiner has interpreted this as what he believes was intended, R_3 , as this is consistent with the other claims and disclosure).

The structures of claim 76 of the instant application and claims 1-7 and 10 of '366 are seen to be substantially overlapping.

Claim 99 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 4-6 U.S. Patent No. 6,686,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Markush groups of both claim sets comprise a compound of the same structure. Claim 99 comprises a compound having the following structure:

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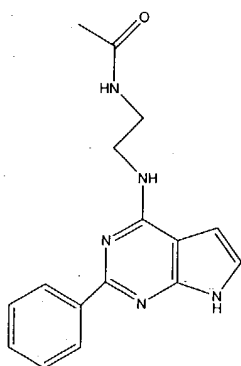
, which is the same as the structure as represented in claims 1 and 4-6 of '366 wherein the variables of '366 are defined as: $m=1$; R_1 (of claim 6) is aminomethyl; R_3 is substituted aryl; and R_5 and R_6 are H.

Claims 124, and 126-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-29 of U.S. Patent No. 6,686,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to various compositions comprising the same structure as set forth supra, together with a carrier.

Claims 133-135 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-46 of U.S. Patent No. 6,686,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of preparing the same compounds, as set forth supra, with the same methodological steps and the same reactants.

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Claim 76 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 6,680,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications comprise the following structure in their representative claims:



, wherein in the instant applications claim 76 R_1 is acetamido ethyl, and R_5 and R_6 are H.

Claims 124, and 127, and 129-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-33 of U.S. Patent No. 6,680,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to various compositions comprising the same structure as set forth supra, together with a carrier.

Claim 133 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims and 36 of U.S. Patent No. 6,680,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of preparing the same compounds, as set forth supra, with the same methodological steps and the same reactants.

Additionally, applicants are encouraged to ensure that the elected claims of copending application 10/227,378, which has been restricted and is awaiting an election, do not overlap in structure with the claims of the instant application.

Claim Objections

Claim 124 is objected to because of the following informalities: the claim as amended reads "a pharmaceutical composition comprising **a the** compound of claim...", which is confusing. Appropriate correction is required.

Claims 126 and 127 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The intended use of the composition is of no patentable import to the composition, compositions are treated on the merits of the composition itself, not on what they are intended to be used to treat.

Claim Rejections - 35 USC § 112

Claim 123 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

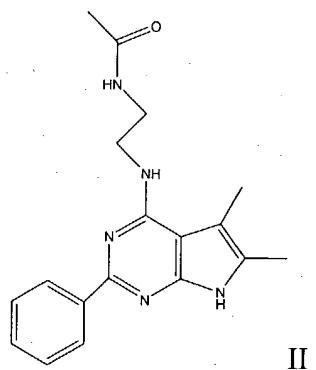
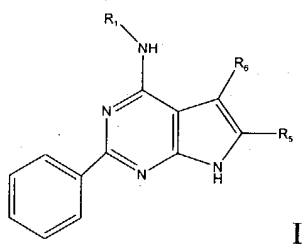
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Claim 123 is indefinite wherein the claim is drawn to a combination therapy, however, the claim is silent in respect to any therapeutic steps which are to be practiced in the therapy. It appears that applications are claiming a composition to be used in treating glaucoma.

Claim Rejections - 35 USC § 102

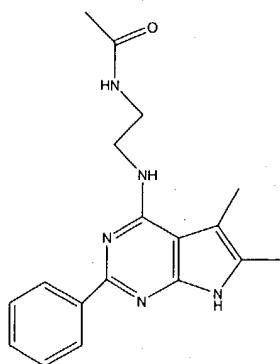
Claim 76 is rejected under 35 U.S.C. 102(a) as being anticipated by Campbell et al. ("Selective A₁-Adenosine Receptor Antagonists Identified Using Yeast *Saccharomyces cerevisiae* Functional Assays", Bioorganic & Medicinal Chemistry Letters, vol. 9, no. 16, 8.16.1999, pp. 2413-18) of record.

Claim 76 is drawn to a compound represented by the structure I below, when R₅ and R₆ are methyl, and R₁ is acetamido ethyl, the structure II is formed:



Campbell et al. disclose a compound 4C on page 2414, bottom table, and page 2415, product 4 of scheme 1 which is represented by the structure:

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which is identical to the compound as represented by formula II above.

The compound of Campbell et al. is seen to clearly anticipate the compound of claim 76.

Conclusion

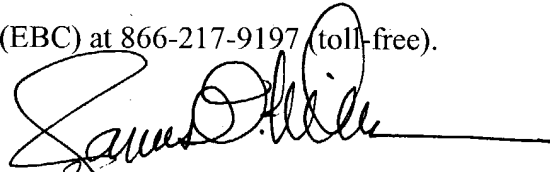
Claims 77-110 and 114-122 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or fairly suggest the N-6 substituted 7-deazapurine compounds as set forth in claims 77-98, nor the methods of making or the methods of using the same. Nothing in the art of record is seen to motivate the skilled artisan to modify the core 7-deazapurine as applicants have done.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh III
February 6, 2004